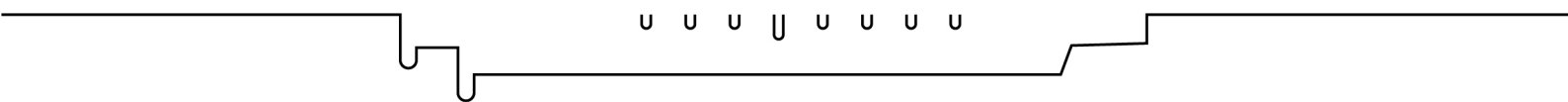


INSTRUCTION FOR USE

Disposable Sterile Syringe For Insulin



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1. Intended use

The product is suitable for disposable insulin injection, the insulin solution was aspirated and immediately inject to the human body.

1) Intended users: patients trained in insulin injection and medical professionals (including doctors, nurses, etc.).

2) Intended use environment: This instrument is mainly used in medical institutions and patients who need to inject insulin.

3) Intended patient population:

① Age group: unlimited, including newborns to the elderly;

② Weight range: all;

③ Health: patients who need to complete insulin injection with a syringe.

4) The type of body part or tissue with which it interacts:

The device will have direct contact with the patient's skin, tissue, blood path;

Body parts: Injected subcutaneously.

5) Intended clinical efficacy:

① Control blood sugar level: insulin syringe can help diabetes patients to inject insulin quantitatively when needed to control blood sugar level.

② Prevention of complications: through the rational use of insulin injectors, diabetes patients can stabilize blood sugar levels, thereby reducing and delaying various complications that diabetes may cause.

③ Improve the quality of life: The use of insulin injectors can improve the quality of life of patients with diabetes. It can allow patients to more freely control their diet and exercise, and avoid high or low blood sugar levels before or after meals.

④ Personalized treatment: Insulin injectors can be personalized and adjusted according to individual differences and needs of patients, achieving more accurate insulin dosage and administration time, and improving treatment effectiveness.

But insulin injectors are only a treatment method, and their efficacy is influenced by various factors, including patient compliance behavior, insulin usage methods, and so on. Before using insulin injectors, it is recommended to consult a doctor or professional medical staff for guidance and strictly follow their instructions for use.

2. Product description

Syringe type: Type 1, 2, 3, 4;

Type 1: The syringe has a 6% Luer taper joint, which is composed of a barrel, a plunger rubber plug and a plunger;

Type 2: The syringe has a 6% Luer taper joint, which is composed of a barrel, a plunger rubber plug, a plunger and protective end caps;

Type 3: The syringe has a 6% Luer taper joint and is composed of a barrel, a plunger rubber plug, a plunger and an optional accessory - the injection needle;

Type 4: The syringe has a 6% Luer taper joint, which is composed of a barrel, a plunger rubber plug, a plunger, protective end caps and an optional accessory - the injection needle;

The round taper joint of syringe has two types: luer slip and luer lock.

The barrel, plunger and protective end caps are made of medical polypropylene material, the needle tube is made of medical stainless steel material, and the piston and needle are purchased products with valid registration certificate of medical devices.

Unit scale: U-100(Nominal capacity :1.0ml),U-40(Nominal capacity :1.0ml).

Optional - needles specifications: 0.25(31G), 0.30(30G), 0.33(29G), 0.36(28G), 0.40(27G), 0.45(26G),0.50 (25G).

All materials of the product meet medical requirements, the concentration of CMR and or endocrine disrupting substances does not exceed 0.1% by weight, and does not contain radioactive substances.

The biological, chemical and physical properties of the products meet the requirements of the product standards.

Clear scale range, capacity tolerance in accordance with ISO 8537(latest edition), measurement functions meet the requirements of Table 1:

The product is sterilized by ethylene oxide.

This product is not a combination of pharmaceutical devices.

This product is a Class IIa sterile medical device, not implantable.

Basic UDI-DI: 69541527202202aJYZQFU

The full UDI-DI record is available in the EUDAMED database.

CE Marking: CE 0123 – Conformity assessed under MDR by Notified Body TÜV SÜD Product Service GmbH Certification Body.

Table 1

Unit scale	Nominal Capacity mL	Minimum length of scale mm	Scale interval units	Tolerance on graduated capacity	
				Volumes less than half the nominal capacity	Volumes equal to or greater than half the nominal capacity
U-100	1.0	57	1	±1.5 % of the nominal capacity +2 % of the expelled volume	±5 % of the expelled volume
	1.0	57	2		
U-40	1.0	50	1		

3.Instructions for use

- 1) Use in time after opening sterile packaging;
- 2) Connect the hypodermic needle and remove the needle cap;
- 3) Fill the syringe, correctly adjust and read the scale of the required drug dosage;
- 4) After filling the syringe with liquid, please use it immediately;
- 5) After use, please destroy according to relevant regulations on medical device waste treatment;
- 6) This device is sterile medical device and can be used independently.

4. Contraindication

This device is intended solely for subcutaneous insulin delivery as prescribed by a physician. It is contraindicated in patients with known hypersensitivity to any of the materials used in the device . It must not be used for any other type of injection or medication unless explicitly approved.

5. Precautions and warnings

- 1) If the aseptic package is damaged or accidentally opened, the protective cover of the injection needle falls off, the scale is unclear or incomplete, there is foreign body or product damage, it is prohibited to use;
- 2) Expired prohibited use;
- 3) This product is for one-time use only, and repeated use is prohibited;
- 4) Waste shall be disposed in accordance with relevant medical device disposal regulations and other provisions, and shall avoid being pricked by needles;
- 5) If the injection needle is damaged, do not use it;
- 6) Avoid moisture, heat and pollution;
- 7) In the event of any serious incident related to the device, the user or patient should immediately report it to the manufacturer and to the competent authorities of the country in which it is located;
- 8) People who do not inject insulin should not use it;
- 9) Use the syringe immediately after inhaling the liquid;
- 10) The use of this product must meet the requirements of the relevant operating norms and relevant regulations of the medical department, and is limited to trained doctors, nursing staff and other medical professionals and patients who have received training in insulin injection. The use of this product is prohibited without trained personnel;
- 11) Some patients may experience redness, swelling, pain, bleeding and papules after injection;
- 12) In order to reduce the pain at the puncture site and prevent thrombophlebitis, continuous or repeated puncture at the same site is not recommended.

6. Validity period, production date and/or expiration date

Validity period: 5 years. The production date and/or expiration date are detailed on the packaging.

7. Storage, transportation and maintain

The product should be stored in a cool, dry, clean, well-ventilated environment without corrosive gas, and prevent direct sunlight and rain and snow from wetting.

Drawing	Meaning
	“CE mark”

	"DO NOT USE IF PACKAGE IS DAMAGED"
STERILE EO	"STERILE" by EO sterilization
	"DO NOT REUSE", "single use", "Use only once"
SBS	"Sterile barrier system/sterile packaging"
	"Non-sterile protective packaging with sterile barrier system inside"
	" LATEX FREE"
	"DATE OF MANUFACTURE"
	"Consult instructions for use"
	"CAUTION"
	"Keep away from sunlight"
	"Fragile,handle with care"
	"Expiry date"
	"MANUFACTURER"
LOT	"BATCH CODE"
EU REP	"Authorized representative in the European Community"
CH REP	"Authorized representative in the Switzerland"

8. Handling of Adverse Events

In the event of a serious incident (e.g., needle breakage, sterility breach, patient injury), Report immediately to Email: zhzjb@kdlchina.com;

National Competent Authority: Use the EU portal: <https://www.adrreports.eu>

Provide: device name, UDI, batch number, description of incident, and patient outcome.



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